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(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
10 October 2002 (10.10.2002)

PCT

(10) International Publication Number  
**WO 02/078568 A1**

(51) International Patent Classification<sup>7</sup>: **A61F 2/00**

(21) International Application Number: PCT/GB02/01234

(22) International Filing Date: 2 April 2002 (02.04.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
0108088.6 30 March 2001 (30.03.2001) GB

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(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: SURGICAL IMPLANT

(57) Abstract: A surgical implant suitable for treatment of hernias is provided. The implant comprises a mesh having a residual maximum mass density of 50g/m<sup>2</sup>. The mesh comprises strands forming spaces and the strands comprise filaments forming pores. The spaces and pores are sized to minimise foreign body mass for implantation and to encourage integration of the implant. The mesh may be delivered using Dual Phase Technology™ for ease of handling, cutting and placement. The Dual Phase Technology™ may include encapsulation or coating with hydrogel.

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1     **"Surgical Implant"**

2

3     The present invention relates to the treatment of a  
4     hernia such as a uterovaginal prolapse and, in  
5     particular, to a surgical implant for use in such  
6     treatment and to a related surgical procedure and  
7     device.

8

9     A hernia is basically a defect resulting in the  
10    protrusion of part of an organ through the wall of a  
11    bodily cavity within which it is normally contained.  
12    For example, a fairly common and well known type of  
13    hernia is a defect in the lower abdominal wall  
14    resulting in a sac which may contain a portion of  
15    the intestine protruding through the abdominal wall.  
16    This is referred to as an inguinal hernia.  
17    Similarly, a defect in the abdominal wall after  
18    surgery is referred to as an incisional hernia.  
19    Another type of hernia is a defect in the pelvic  
20    floor or other supporting structures resulting in a  
21    portion of the uterus, bladder, bowel or other  
22    surrounding tissue protruding through, e.g., the

1 vaginal wall. This is usually referred to as  
2 uterovaginal prolapse.

3  
4 A common way of treating hernias is to repair the  
5 defect by sutures, whether or not the hernial sac is  
6 also sutured or repaired, in order that the  
7 protruding organ is contained in its normal  
8 position. As the defect generally comprises a  
9 weakening and attenuation leading to parting of  
10 tissues in a fascial wall, it is usually necessary  
11 to apply tension to the sutures in order to close  
12 the parted tissues. Thus, the fascial wall is  
13 generally pinched or tensioned around the area of  
14 the defect in order to close the parted tissues.

15  
16 This treatment is generally effective, but does have  
17 some inherent problems. In particular, the pinching  
18 or tensioning of tissue around the defect can lead  
19 to discomfort and/or recurrence of the hernia.  
20 Additionally, in the case of uterovaginal prolapse,  
21 such pinching or tensioning of the vaginal wall  
22 almost inevitably results in anatomical distortion  
23 (such as narrowing of the vaginal cavity) with  
24 consequential pain and quality of life implications  
25 for the patient and relatively high recurrence  
26 and/or complication rates.

27  
28 In order to address these problems, in the case of  
29 inguinal hernia repair, it has been suggested to  
30 make use of a surgical implant to overlay or close  
31 the weakened and parted tissues without the need to  
32 pinch or tension the surrounding tissue of the

1 fascia. Such surgical implants generally comprise  
2 meshes and are now widely used in inguinal hernia  
3 repair. Meshes may be applied subcutaneously (i.e.  
4 under the skin), internally or externally of the  
5 abdominal wall and may be either absorbable or non-  
6 absorbable depending on the nature and severity of  
7 the particular defect being treated. Meshes may be  
8 applied in combination with sutures to hold the mesh  
9 in place or, alternatively, with sutures that close  
10 the parted tissues as in a "non-mesh" technique.  
11 Meshes are usually applied in open surgical  
12 procedures, although they may sometimes be applied  
13 in laparoscopic surgical procedures.

14

15 A typical mesh for an inguinal hernia repair  
16 comprises woven or knitted polypropylene such as  
17 Marlex® or Prolene®. Such meshes have a number of  
18 desirable properties that make them effective for  
19 use in hernia repair. For example, they are made of  
20 materials that are suitably inert so as to be less  
21 likely to cause adverse reactions when implanted in  
22 the body. Furthermore, they are mechanically  
23 strong, cheap, easily sterilisable and easy to work  
24 with.

25

26 However, conventional meshes have a number of  
27 inherent problems. For example, fistula or sinus  
28 (i.e. abnormal passages between internal organs or  
29 between an internal organ and the body surface) can  
30 develop as a result of a mesh being implanted and  
31 left inside the body. More generally, the placement  
32 of a foreign body subcutaneously can also lead to

1 inflammation or infection. Similarly, edge extrusion  
2 (i.e. the erosion of body tissue around the edge of  
3 the mesh) can occur. Nevertheless, overall, the use  
4 of meshes is generally considered to be beneficial  
5 in the treatment of incisional and inguinal hernias.

6  
7 It has also been suggested to use meshes in the  
8 treatment of uterovaginal prolapse. Meshes that  
9 have been proposed for use in the repair of  
10 uterovaginal prolapse are similar to those that are  
11 used for the repair of inguinal hernia and such  
12 like. However, there is concern that the above  
13 mentioned problems with the use of meshes are  
14 greater when a mesh is placed in the vaginal wall as  
15 this tissue is generally thin only just below the  
16 surface and therefore more prone to adverse  
17 reactions. Furthermore, the placement of a foreign  
18 body close to the rectum and urinary tract may  
19 increase the risk of infection, inflammation,  
20 erosion, fistula or translocation. Thus, it is a  
21 relatively widespread view that the use of meshes in  
22 the treatment of vaginal prolapse is less desirable  
23 than in the treatment of other hernias.

24  
25 Nevertheless, as the use of meshes to treat  
26 uterovaginal prolapse can avoid anatomical  
27 distortion and the above mentioned problems related  
28 to this, the Applicant considers there are  
29 significant benefits in the use of meshes in the  
30 treatment of uterovaginal prolapse should it be  
31 possible to mitigate the problems associated with  
32 mesh treatment.

1 The applicant has recognised that there are a number  
2 of specific features of conventional meshes that  
3 exacerbate the problems of fistula, sinus, edge  
4 extrusion, infection etc., particularly when these  
5 meshes are implanted in the vaginal wall. The  
6 Applicant has therefore realised that it is possible  
7 to provide a surgical implant that has the benefits  
8 of mesh treatment, i.e. the avoidance of anatomical  
9 distortion and its related problems, and also  
10 minimises the above mentioned problems.

11  
12 One specific problem with conventional meshes that  
13 the Applicant has recognised is that they have  
14 jagged or rough edges. The rough edges arise as  
15 conventional meshes are generally formed from sheets  
16 of multiple woven or intersecting fibres or strands.  
17 When the meshes are cut to size in manufacture or  
18 prior to fitting, the stray ends of the fibres or  
19 strands are left extending from the edge of the  
20 mesh, particularly where the edge is curved. In  
21 other words, the perimeter of the mesh comprises the  
22 spaced ends of the fibres or strands and is not  
23 smooth. It is thought that the jagged rough nature  
24 of the edges of the implant increases the likelihood  
25 of extrusion of the edge of the mesh *in situ*.

26  
27 Conventional meshes are generally unnecessarily  
28 strong and substantial for use in the vaginal wall  
29 and of significant mass. This results in an  
30 unnecessary excess of foreign body material in the  
31 vaginal wall, increasing the risks associated with  
32 the placement of foreign bodies inside the human

1 body, such as the risk of infection. Likewise, the  
2 bulk of such meshes can undesirably result in  
3 discomfort for the patient as the mesh can often be  
4 felt when in position. This is of particular  
5 concern when a mesh is placed in sensitive vaginal  
6 tissues or near to bowel or bladder.

7  
8 A further disadvantage of the meshes presently used  
9 to treat hernias relates to pore size. The pore  
10 size of meshes in use is unphysiological and does  
11 not encourage acceptance of the implant in the body.

12  
13 It is a aim of the present invention to overcome  
14 problems associated with existing meshes used to  
15 treat hernias.

16  
17 According to the present invention there is provided  
18 a surgical implant suitable for treatment of  
19 hernias, the implant comprising a mesh having a  
20 residual maximum mass density of  $50\text{g/m}^2$ .

21  
22 Preferably the maximum mass density is less than  
23  $30\text{g/m}^2$ . More preferably the maximum mass density is  
24 less than  $25\text{g/m}^2$ .

25  
26 By minimising mass density of a mesh for use in  
27 treating hernias the advantages of using a mesh are  
28 still apparant whereas the disadvantages are  
29 lessened in that jagged and rough edges are  
30 minimised as is the risk of infection. The residual  
31 mass density is the mass density of the mesh after  
32 implantation.

1 Preferably the surgical implant mesh comprises  
2 strands and includes major spaces and pores.

3  
4 The strands of the mesh may be formed by at least  
5 two filaments, the major spaces formed between the  
6 strands providing the surgical implant with the  
7 necessary strength, the filaments arranged such that  
8 pores are formed in the strands of the mesh.

9  
10 Alternatively the strands may be formed by  
11 monofilaments which form loops which give rise to  
12 the pores.

13  
14 Preferably strands are spaced by wider distance than  
15 the fibres or filaments of conventional meshes used  
16 in hernia repair.

17  
18 Preferably the strands are spaced apart to form  
19 major spaces of between 1 to 10 mm.

20  
21 More preferably the strands are spaced apart to form  
22 major spaces of between 2 to 8 mm.

23  
24 The use of mesh having strands spaced between 1 to  
25 10 mm apart has the advantage of reducing the  
26 foreign body mass that is implanted in the human  
27 body. Only sufficient tensile strength to securely  
28 support the defect and tissue being repaired is  
29 provided by the mesh.

30  
31 It is desirable that the mesh of the present  
32 invention has a mass of between one tenth (1/10th)



1 and one hundredth (1/100th) that of a conventional,  
2 e.g. Prolene®, mesh of the same surface area. The  
3 mesh of the invention therefore avoids the  
4 unnecessary bulk of conventional meshes.

5  
6 More specifically it is preferred that the mass  
7 density is less than 50g/m<sup>2</sup>, more preferably less  
8 than 30g/m and most preferably less than 20g/m<sup>2</sup>.  
9 It is also preferred that the strands of the mesh of  
10 the present invention are narrower than those of  
11 meshes of the prior art.

12  
13 Preferably the strands have a diameter of less than  
14 600µm.

15  
16 In one embodiment the strands are arranged to form a  
17 diamond net mesh.

18  
19 In an alternative embodiment the strands are  
20 arranged to form a hexagonal net mesh.

21  
22 The strands and filaments are preferably warp knit.

23  
24 In an alternative embodiment the strands are  
25 arranged to form a net mesh with suitable tensile  
26 strength and elasticity.

27  
28 Preferably the strands are arranged to form a net  
29 mesh which has isotropic or near isotropic tensile  
30 strength and elasticity.

31

1 Preferably the filaments have a diameter of between  
2 0.02 to 0.15 mm.

3

4 More preferably the filament of the mesh is of a  
5 diameter 0.08 to 0.1 mm.

6

7 This likewise has the advantage of reducing the  
8 overall bulk of the implant, and hence the amount of  
9 material retained in the human body.

10

11 Particular meshes which are embodiments of the  
12 present invention include warp knit diamond or  
13 hexagon net diamond net meshes. Four particular  
14 embodiments are set out below.

15

16 In two particular embodiments wherein the filaments  
17 are formed from polypropylene having a diameter of  
18 0.07 - 0.08mm wherein the strands are spaced to form  
19 spaces of either 2mm or 5mm.

20

21 Alternatively, filaments are formed from polyester  
22 having a diameter of 0.09mm wherein the strands are  
23 spaced to form spaces of 5mm.

24

25 Alternatively, filaments are formed from polyester  
26 having a diameter of 0.05 - 0.07mm wherein the  
27 strands are spaced to form spaces of 2mm.

28

29 As the surgical implant is comprised of narrow  
30 members arranged to be spaced by relatively wide  
31 gaps, major spaces, tissue may be slow to grow into  
32 the mesh. It is desirable for the mesh to have

1 means for promoting tissue ingrowth. More  
2 specifically, it is desirable to provide pores in  
3 the strands of the mesh to aid tissue ingrowth and  
4 to which tissue may more easily adhere.

5

6 Preferably two filaments are interwoven/knitted to  
7 produce strands of the mesh comprising pores.

8

9 Alternatively at least three filaments are  
10 interwoven/knitted to produce strands of the mesh  
11 comprising pores.

12

13 For manufacturing reasons it is preferred that two  
14 filaments are used to form the pores in the strands  
15 of the mesh which aid tissue ingrowth, however if  
16 the one filament could be suitably knotted or  
17 twisted to form pores of suitable dimensions it is  
18 clear that this could be used to similar effect to  
19 form the strands of the mesh.

20

21 Preferably the pores in the strands are of between  
22 50 to 200µm in diameter.

23

24 More preferably the pores are of between 50 to 75µm  
25 in diameter.

26

27 This is important in enabling efficient fibroblast  
28 throughgrowth and ordered collagen laydown in order  
29 to provide optimal integration into the body. This  
30 is discussed in detail in copending Patent  
31 Application No PCT/GB01/04554.

32

1 Rings or loops of material comprising pores of  
2 between 50 to 200µm may be adhered to or formed on  
3 the strands of the mesh to provide pores.

4  
5 As mentioned above, reducing the mass of the mesh  
6 has distinct advantages in relation to the  
7 suitability of the mesh for implantation in the  
8 body, i.e. the reduction of foreign body mass and  
9 improving the comfort of the patient. However, the  
10 handling characteristics of such a mesh, e.g. the  
11 ease with which a surgeon can manipulate and place  
12 the surgical implant in its desired location in the  
13 body, can be poor in some circumstances. More  
14 specifically, a mesh having narrow members or  
15 strands that are widely spaced will inevitably be  
16 somewhat flimsy and lacking in rigidity compared to  
17 conventional meshes.

18  
19 Ideally the implant should be formed from materials  
20 or uses technologies which provide the implant with  
21 Dual Phase Technology™, such that it has suitable  
22 surgical handling characteristics and is also of  
23 minimal mass and suited for implantation in the  
24 body. The implant may be formed from a range of  
25 materials to provide it with Dual Phase  
26 Technology™.

27 The term Dual Phase Technology™ refers to a means  
28 to provide temporary substance to the mesh.

29 Depending on the type of Dual Phase Technology™  
30 employed the benefits imported, in addition to  
31 allowing minimal residual mesh mass may include  
32 assisting the mesh to be handled and cut, minimising

1 the effect of rough edges, assisting placing the  
2 mesh in position and providing tackiness to assist  
3 in holding the mesh in position on implantation,  
4 thus minimising or negating the need for any  
5 additional fixation by suturing or adhesion.

6

7 In a preferred embodiment of the invention having  
8 improved handling characteristics, the implant  
9 therefore has an absorbable coating.

10 Preferably this coating encapsulates the mesh of the  
11 surgical implant.

12

13 Alternatively this coating is applied to at least  
14 one face of the mesh.

15

16 The coating, covering or layer of absorbable  
17 material stiffens and adds bulk to the mesh such  
18 that it is easier to handle.

19

20 As the coating, covering or layer is absorbable, it  
21 is absorbed by the body after implantation and does  
22 not contribute to the foreign body mass retained in  
23 the body. Thus, the advantages of a surgical  
24 implant having minimal mass are retained.

25

26 Preferably the coating, covering or layer absorbs  
27 within 48 hours following implantation.

28

29 The coating, covering or layer may comprise any  
30 suitable soluble and biocompatible material.

31

1     Suitable hydrogel materials can be obtained from  
2     First Water in the UK. A typical hydrogel being  
3     developed for use in this application is known as  
4     FIRST PHASE™ or PHASE 1™.

5  
6     The absorbable material may be a soluble hydrogel  
7     such as gelatin,

8  
9     Alternatively the absorbable material is a starch or  
10    cellulose based hydrogel.

11  
12    In a further alternative the absorbable material is  
13    an alginate.

14  
15    In a further alternative the absorbable material may  
16    contain hyaluronic acid.

17  
18    The coating, covering or layer may have any  
19    thickness or bulk that provides the surgical implant  
20    with suitable handling characteristics.

21  
22    Preferably, the coating is a sheet with a thickness  
23    greater than that of the mesh.

24  
25    Suitable handling characteristics may also be  
26    provided to the mesh by a range of other methods.

27    The surgical implant may comprise a mesh and a  
28    backing strip the backing strip releasably  
29    attachable to the mesh.

30  
31    The backing strip may be formed from a range of  
32    materials including plastics.

1 The surgical implant may be releasably attachable to  
2 the backing strip by adhesive.

3

4 The releasable attachment of a backing strip to the  
5 mesh provides a more substantial and less flexible  
6 surgical implant that is more easily handled by a  
7 surgeon. Following suitable placement of the  
8 surgical implant the backing strip can be removed  
9 from the surgical implant, the surgical implant  
10 being retained in the body and the backing material  
11 being removed by the surgeon. The surgical implant  
12 can therefore benefit from reduced mass while still  
13 providing characteristics required for surgical  
14 handling.

15

16 In a further alternative the strands of the mesh of  
17 the surgical implant are comprised of bicomponent  
18 microfibres.

19

20 Preferably the bicomponent microfibres comprise a  
21 core material and surface material.

22

23 The composite or biocomponent fibres preferably  
24 comprise a nonabsorbable or long lasting absorbable  
25 core and a shorter lasting absorbable surface  
26 material.

27

28 Whereas any licenced materials may be used, suitable  
29 materials presently available include polypropylene  
30 for the core and polylactic acid or polyglycolic  
31 acid for the surface materials.

1     Alternativley the bicomponent microfibres comprise  
2     an material which is rapidly absorbed by the body  
3     and a material which is not absorbed for a suitable  
4     longer period of time.

5

6     Preferably the surface material is capable of being  
7     absorbed by the body in a period of less than 48  
8     hours.

9

10    Preferably the core material is capable of remaining  
11    in the body for a period of time sufficient to  
12    enable tissue ingrowth.

13

14    The surface material of the bicomponent microfibres  
15    or a portion of the composite polymers present  
16    during the insertion and placement of the surgical  
17    implant provides the surgical implant with  
18    characteristics required for surgical handling.

19

20    Following a period of insertion in the body, the  
21    surface material of the bicomponent microfibre is  
22    absorbed by the body leaving behind the reduced  
23    foreign mass of the core material of the strands of  
24    the mesh.

25

26    It is preferred that the surface material of the  
27    bicomponent microfibre is absorbed by the body  
28    within a number of hours such that only a core  
29    portion is left in the body for an extended length  
30    of time. Typically materials presently available  
31    which could be used to form the microfibres are  
32    absorbed by the body over a period of days or weeks.



1 The filaments of the mesh comprise a plastics or  
2 synthetic material.

3  
4 Preferably the filaments of the mesh comprise of  
5 polypropylene or polyester.

6  
7 Alternatively the filaments of the mesh comprise an  
8 absorbable material.

9  
10 It can be appreciated that filaments which comprise  
11 in part of absorbable material would allow better  
12 surgical handling, but would enable the implant to  
13 also have minimal mass following implantation in the  
14 body.

15  
16 Preferably the surgical implant comprises material  
17 that has memory.

18  
19 Preferably the surgical implant has memory which  
20 urges the surgical implant to adopts a flat  
21 conformation.

22  
23 Preferably the implant has a generally curved  
24 perimeter, i.e. to have few or no corners or apexes,  
25 as sharp corners increase the likelihood of edge  
26 erosion and infection. The specific shape will,  
27 however, vary according to the use to which the  
28 implant is to be put.

29  
30 Due to the variety of sizes of such defects, and of  
31 the various fascia that may need repair by the  
32 implant, the implant may have any suitable size,

1 Preferably the surgical implant is of width between  
2 1 cm to 10 cm and of length between 1 cm to 10 cm.

3

4 It may be desirable to provide a variety of implants  
5 having different sizes in order that a surgeon can  
6 select an implant of suitable size to treat a  
7 particular patient. This allows implants to be  
8 completely formed before delivery, ensuring, for  
9 example, that the smooth edge is properly formed  
10 under the control of the manufacturer. The surgeon  
11 would have a variety of differently sized (and/or  
12 shaped) implants to hand and select the appropriate  
13 implant to use after assessment of the patient.

14

15 Typically an anterior uterovaginal prolapse is  
16 ellipse shaped or a truncated ellipse whereas a  
17 posterior prolapse is circular or ovoid in shape.

18

19 Accordingly the implant shape may be any one of  
20 elliptical or truncated ellipse, round, circular,  
21 oval, ovoid or some similar shape to be used  
22 depending on the hernia or prolapse to be treated.

23

24 Different shapes are suitable for repairing  
25 different defects in fascial tissue and thus by  
26 providing a surgical implant which can be cut to a  
27 range of shapes a wide range of defects in fascial  
28 tissue can be treated.

29

30 Preferably the mesh can be cut to any desired size.  
31 The cutting may be carried out by a surgeon or nurse  
32 under sterile conditions such that the surgeon need

1 not have many differently sized implants to hand,  
2 but can simply cut a mesh to the desired size of the  
3 implant after assessment of the patient. In other  
4 words, the implant may be supplied in a large size  
5 and be capable of being cut to a smaller size, as  
6 desired.

7  
8 In this regard, whilst the surgical implant of the  
9 invention is particularly useful for the repair of  
10 uterovaginal prolapse, it may be used in a variety  
11 of surgical procedures including the repair of  
12 hernias.

13  
14 Preferably the surgical implant is suitable for use  
15 in the treatment of hernias including incisional and  
16 inguinal hernias and/or for the treatment of  
17 uterovaginal prolapse.

18  
19 More broadly, the Applicant has therefore recognised  
20 that the implant can have any shape that conforms  
21 with an anatomical surface of the human or animal  
22 body that may be subject to a defect to be repaired  
23 by the implant.

24  
25 As discussed a disadvantage of the meshes used in  
26 hernia repair is that they have jagged or rough  
27 edges. Due to the wide spacing between strands of  
28 the mesh described above and the small diameter of  
29 the filaments, the edge problems are mitigated to an  
30 extent by the present invention.

31

1 To further reduce edge problems it would be  
2 preferable if a mesh had a circumferential member  
3 which extends, in use, along at least part of the  
4 perimeter of the implant to provide a substantially  
5 smooth edge.

6  
7 In other words, the mesh has at least one  
8 circumferential member (i.e. fibre, strand or such  
9 like) that extends around at least part of its  
10 circumference.

11  
12 Preferably at least part of the perimeter of the  
13 implant is defined by the circumferential member,  
14

15 Alternatively at least part of the perimeter of the  
16 implant is defined by more than one circumferential  
17 member, at the edge of the mesh.

18  
19 The edge of the mesh, and hence the perimeter of the  
20 implant, can therefore be generally smooth and this  
21 has significant advantages over conventional  
22 surgical meshes. Specifically, the Applicant has  
23 recognised that an implant having a smooth edge is  
24 less likely to cause edge extrusion or erosion.

25  
26 Any amount of the perimeter of the implant may be  
27 defined by the circumferential member(s).

28  
29 However, in order to maximise the benefits of the  
30 implant of the invention, it is preferable that at  
31 least 50% of the perimeter of the implant is defined  
32 by the circumferential member(s)..

1 More preferably at least 80% of the perimeter of the  
2 implant is defined by the circumferential member(s).

3

4 Most preferably 100% of the perimeter of the implant  
5 is defined by the circumferential member(s).

6

7 The majority or the whole of the perimeter of the  
8 mesh being smooth minimises the risk of a rough edge  
9 causing edge erosion or infection.

10

11 The circumferential member(s) may be arranged in one  
12 of a variety of ways to provide the smooth edge or  
13 perimeter.

14

15 Preferably the circumferential members are arranged  
16 such that they each follow the edge of a desired  
17 shape of the surgical implant, the perimeter of the  
18 implant formed from as few members as possible.

19

20 This simplifies the construction of the mesh, which  
21 is desirable not only for manufacture, but also  
22 because simpler structures are less likely to have  
23 defects which might be problematic after  
24 implantation.

25

26 Preferably the perimeter of the mesh is defined, in  
27 use, by one circumferential member.

28

29 Preferably the mesh has a plurality of  
30 circumferential members arranged at different radial  
31 locations.

32

1 In order to provide an implant of given dimensions,  
2 the periphery of the mesh outward of the desired  
3 circumferential member is cut away such that one or  
4 more selected circumferential members form the  
5 perimeter of the implant as desired.

6

7 More preferably, the circumferential members are  
8 arranged concentrically.

9

10 A concentric arrangement of a plurality of  
11 circumferential members conveniently allows  
12 maintenance of the shape of the implant for  
13 different sizes of implant and provides the mesh  
14 with an even structure.

15

16 The remainder of the structure of the mesh may take  
17 a variety of forms.

18

19 The circumferential members can be arranged to join  
20 with one another in order to form an integral mesh.

21

22 Alternatively the mesh may additionally comprise  
23 transverse members which extend across the  
24 circumferential members joining the circumferential  
25 members.

26

27 The transverse members may extend radially from a  
28 central point to the perimeter of the implant.

29

30 Alternatively, the transverse members may extend  
31 toward the perimeter of the implant.

32

1 Preferably the transverse members are arranged to  
2 provide substantially even structural strength and  
3 rigidity to the implant.

4  
5 It may be desirable to secure the mesh in place once  
6 it has been suitably located in the patient.

7  
8 Preferably the mesh can be sutured to strong lateral  
9 tissue.

10  
11 Alternatively, the mesh may be glued in place using  
12 a biocompatible glue.

13  
14 This is advantageous, as it is fairly quick to apply  
15 glue to the area around the surgical implant.

16  
17 Preferably the mesh comprises at least one capsule  
18 containing biocompatible glue for securing the  
19 implant in place.

20  
21 Preferably 4 capsules containing glue are provided  
22 around the perimeter of the surgical implant.

23  
24 Preferably the capsules comprise hollow thin walled  
25 spheres of around 3 to 5 mm diameter including  
26 gelatin.

27  
28 Preferably the glue is a cyanoacrylate glue.

29  
30 Conventionally, open procedures have been preferred  
31 for the treatment of hernias with meshes, as  
32 relatively broad access is required to the site of

1 the defect to suitably implant and secure a mesh by  
2 sutures or such like.

3  
4 However, it is desirable to treat hernias, as when  
5 carrying out any surgery, with as little trauma to  
6 the patient as possible. Thus, the use of minimally  
7 invasive techniques has been suggested for the  
8 treatment of hernias. However, such surgical  
9 techniques have not been considered to be useful in  
10 the treatment of uterovaginal prolapse with a mesh,  
11 as it has not been considered practical to position  
12 a mesh subcutaneously in the vaginal wall due to the  
13 difficulty in gaining direct access to this area.

14  
15 According to another aspect of the present  
16 invention, there is provided a minimally invasive  
17 method of treating uterovaginal prolapse, the method  
18 comprising the steps;

19  
20 making an incision in the vaginal wall close to  
21 the opening of the vaginal cavity and,

22  
23 making a subcutaneous cut, through the  
24 incision, over and surrounding the area of the  
25 prolapse, which cut is substantially parallel  
26 to the vaginal wall; and

27  
28 inserting a mesh according to the present  
29 invention, through the incision, into the space  
30 defined by the cut.

31



1 Thus, a mesh or the surgical implant such as that  
2 according to the invention can be inserted through a  
3 small incision (e.g. around 1cm to 2 cm in length)  
4 at or in the region of the periphery or opening of  
5 the vaginal cavity. An incision in this position is  
6 easier for a surgeon to access than an incision  
7 deeper in the vaginal cavity, yet the Applicant has  
8 realised that it is also convenient to treat vaginal  
9 prolapse by implanting a mesh in a surgical  
10 procedure carried out entirely through such an  
11 incision.

12  
13 Preferably, the incision is at the anterior or  
14 posterior extremity of the prolapse sac of the  
15 vaginal cavity.

16  
17 This is desirable as prolapse most often occurs in  
18 the anterior or posterior vaginal wall, so  
19 positioning the incision in such a location allows  
20 the most convenient access to these parts of the  
21 vaginal wall.

22  
23 The provision of suitable handling characteristics  
24 for the mesh is particularly advantageous when the  
25 mesh is intended to be used in a conventional open  
26 surgical procedure, as the surgeon needs to handle  
27 the implant directly in order to place it in its  
28 desired location.

29  
30 However, the suitable placement particularly in the  
31 treatment of uterovaginal prolapse, by minimally  
32 invasive techniques require the mesh to be as

1 flexible as possible and therefore to have no  
2 absorbable coating or encasement.

3  
4 A flexible, less bulky mesh may be more easily  
5 handled by tools that may be used to carry out the  
6 procedure.

7  
8 Tools that may be used to carry out this procedure  
9 have a number of specific needs that need to be met  
10 that are not presently met by conventional minimally  
11 invasive surgical tools.

12  
13 These specific needs can best be understood by  
14 considering the steps of the surgical procedure of  
15 the invention in turn.

16  
17 The incision is made in the vaginal wall at the  
18 opening of the vaginal cavity. This can be carried  
19 out using a conventional implement such as a  
20 scalpel. It is preferable that the incision is as  
21 small as possible as this reduces trauma to the  
22 patient.

23  
24 A cut is then made in the vaginal wall over the  
25 defect causing the prolapse or hernia. For example,  
26 scissors or another specialised cutting tool can be  
27 inserted through the incision and manipulated to  
28 provide a cut over the defect. The cut is below the  
29 surface of the skin and may provide a space between  
30 an upper (or outer) layer and a lower (or inner)  
31 layer of the vaginal wall, or between the skin and

1 the vaginal wall, in the region of the defect, into  
2 which cavity the mesh can be inserted.

3  
4 Next, the mesh is placed in the space defined by the  
5 cut. It is preferred that the mesh of the invention  
6 is supplied rolled up in order that it can be  
7 inserted through a small incision and unfurled *in*  
8 *situ*, i.e. in its intended position. Thus, it may  
9 be possible for the surgeon to insert the mesh  
10 through the incision by hand. However, this is  
11 likely to result in the incision needing to be large  
12 enough for the surgeon to insert a finger to  
13 manipulate the mesh in the space. This may cause  
14 unnecessary trauma to the patient and can be  
15 difficult for a surgeon to carry out.

16  
17 According to another aspect of the present  
18 invention, there is provided a surgical tool for  
19 delivering a mesh subcutaneously through an  
20 incision, the tool being adapted to radially confine  
21 the mesh during delivery and being operable to  
22 release the mesh in its intended position.

23  
24 Such a tool for placement of a mesh or the surgical  
25 implant of the present invention can insert and  
26 position the mesh or surgical implant in a  
27 convenient and controlled manner through a small  
28 incision. Furthermore, the incision through which  
29 the mesh is inserted need only be as large as the  
30 diameter of the tool, or the tool when carrying the  
31 mesh, which can be significantly smaller than where

1 a surgeon's finger must be able to fit through the  
2 incision.

3  
4 Preferably the tool comprises a housing and  
5 unfurling means the housing and unfurling means  
6 insertable through an incision in the patient, the  
7 housing and unfurling means adapted to accommodate a  
8 rolled up mesh and separable to release the mesh the  
9 unfurling means capable of unfurling the rolled up  
10 mesh without any significant movement around the  
11 area of the incision

12  
13 Preferably, the tool comprises two or more parts,  
14 the parts movable such that in a first position they  
15 house the mesh or surgical implant and, in a second  
16 position the mesh or surgical implant is released.  
17 More preferably the tool comprises two semi-circular  
18 channels, an inner channel having an external  
19 diameter suitable for fitting inside an outer  
20 channel.

21  
22 The channels may be rotatable about a common axis  
23 such that in a first position the open faces of the  
24 channels face one another to form a closed housing  
25 and in a second position the inner channel sits  
26 inside the other channel to release the mesh.

27  
28 Alternative the tool comprises a shaft and  
29 releasable securing means, the shaft adapted such  
30 that the mesh can be rolled around the shaft and  
31 releasable securing means to secure the rolled mesh  
32 in place.

1 In use, the tool is inserted through the incision  
2 with the mesh rolled around the outside of the  
3 shaft. Once the tool has been inserted, the mesh is  
4 released by turning the shaft to unroll the mesh at  
5 the same time as moving the shaft across the space  
6 in which the mesh is being placed.

7  
8 A needle may be used to secure the free, outer end  
9 of the mesh whilst it is unfurled. The needle may  
10 be inserted through the vaginal wall to pin the mesh  
11 in place. Similarly, where the mesh is released  
12 from within a housing, needles may be used to ease  
13 the mesh out of the open housing.

14  
15 In an alternate embodiment, the tool comprises two  
16 or more arms, each of which is releasably attached  
17 at one end to an edge of the surgical implant. The  
18 arms may be movable from a first position in which  
19 they radially confine the mesh to a second position  
20 to unfurl the mesh in its intended position.

21  
22 In one example, the arms are pivotally  
23 interconnected such that they can be manipulated to  
24 move the ends of the arms from the first position to  
25 the second position.

26  
27 In another example the arms may be arranged to  
28 extend radially outward from a housing to move from  
29 the first position to the second position. The  
30 extendable arms may comprise wires arranged to be  
31 extendable and retractable from and into the housing  
32 by operation at an end of the housing.

1 In another example, the arms may be resilient or  
2 sprung elements that can be released from the first  
3 position and move into the second position to which  
4 they are biased, i.e. to unfurl the mesh.  
5

6 As can be appreciated, all of the above embodiments  
7 of the tool are able to unfurl the mesh without any  
8 significant movement around area of the incision.  
9 For example, the pivot can be arranged to coincide  
10 with the incision, the tool rolled around an arc  
11 centred at the incision or the arms operated or  
12 housing opened forward of the incision. Thus, the  
13 incision can be small as no lateral movement is  
14 required at the area of the incision.  
15

16 Embodiments of the present invention will now be  
17 described, by way of example only, with reference to  
18 the accompanying drawings, in which:  
19

20 Figure 1 is an illustration of a hernia;  
21

22 Figure 2 is an illustration of the hernia of  
23 figure 1 when intra-abdominal pressure is  
24 raised;  
25

26 Figure 3 is an illustration of the hernia of  
27 figure 1 after repair in accordance with the  
28 prior art;  
29

30 Figure 4 is an illustration of the hernia of  
31 figure 1 after an alternate repair in  
32 accordance with the prior art;

1

2 Figure 5 is a schematic illustration of the  
3 female human vaginal area;

4

5 Figure 6 is a cross-sectional view of the  
6 female human vaginal area along the line A-A of  
7 Figure 5;

8

9 Figures 7a and 7b illustrate surgical implants  
10 according to the invention having a first  
11 shape;

12

13 Figures 8a, 8b, 8c and 8d illustrate surgical  
14 implants according to the invention having a  
15 second shape;

16

17 Figures 9a, 9b 9c and 9d illustrate surgical  
18 implants according to the invention having a  
19 third shape;

20

21 Figure 10 illustrates a first surgical tool  
22 according to the invention in cross-section;

23

24 Figure 11 illustrates a second surgical tool  
25 according to the invention;

26

27 Figure 12 illustrates a third surgical tool  
28 according to the invention; and

29

30 Figure 13 illustrates a fourth surgical tool  
31 according to the invention.

32

1 Referring to Figures 1 and 2, a hernia, vaginal  
2 prolapse or such like occurs when a fascial wall 1  
3 ruptures, forming a defect 2, i.e. a weakening or,  
4 in this case, parting of the fascial wall 1. An  
5 organ 3, contained by the fascial wall 1 is then  
6 able to protrude through the defect 2. Such  
7 protrusion is illustrated in Figure 2 and occurs  
8 particularly when pressure within the cavity defined  
9 by the fascial wall 1 is raised. For example, in  
10 the case of an inguinal hernia, when a patient  
11 coughs, intra-abdominal pressure is raised and the  
12 intestines may be pushed through the defect 2 in the  
13 abdominal wall.

14

15 Whilst the organ 3 that may protrude through the  
16 defect 2 is usually still contained by some other  
17 membrane 4, the hernia, prolapse or such like is  
18 inevitably painful and liable to infection or other  
19 complications. An effective and desirable treatment  
20 is therefore to close the defect 2 and contain the  
21 organ 3 in its normal position.

22

23 Referring to Figure 3, hernias, vaginal prolapse and  
24 such like are conventionally repaired by providing  
25 sutures 5 across the defect 2 to join the tissues of  
26 the fascial wall 1. In addition, it may be firstly  
27 necessary to plicate (i.e. fold or reduce) the  
28 membrane 4 as this may have stretched due to  
29 distention of the organ 3. Plication of the  
30 membrane 4 corrects the stretching and helps to  
31 relieve pressure on the area of the defect 2 during  
32 healing as the membrane 4 can act to contain the



1 organ 3 to some extent. Plication is generally  
2 achieved by applying sutures 6 to the membrane 4.

3  
4 Referring to Figure 4, it is also a known method of  
5 treating hernias to provide, additionally or  
6 alternatively to sutures, a mesh 7 across the defect  
7 4. This allows for the defect 2 to be repaired  
8 without the parted tissues of the fascial wall 1  
9 necessarily being brought together and for the  
10 defect to heal without the fascial wall 1 being  
11 pinched or tensioned to correct the defect 2.

12  
13 Figure 5 schematically illustrates (a sagittal view  
14 of) the female human vaginal area. The vagina 8 is  
15 illustrated with its anterior portion (front) at the  
16 top of the diagram and the posterior portion (rear)  
17 at the bottom of the diagram. The opening of the  
18 urethra, or urethral meatus, 9 is at the forward or  
19 anterior end of the vagina 8. The central portion  
20 of the vagina 8 forms the vaginal cavity which  
21 terminates at the cervix 10. Spaced from the  
22 rearward or posterior end of the vagina 8 is the  
23 anus 11. Four areas A to D of the vaginal wall 12  
24 are outlined in figure 5. These areas A to D are  
25 those areas of the vaginal wall 12 in which vaginal  
26 prolapse often occurs.

27  
28 Referring to figure 6, which is a cross sectional  
29 view along the line A-A in figure 5, it can be more  
30 clearly seen that the wall 12 of the vagina 8 is  
31 bounded by the bladder 13 and urethra 14, the uterus  
32 15, the small bowel 16 and rectum 17. The small

1     bowel 16 and rectum 17 are separated by the "Pouch  
2     of Douglas" PoD.

3  
4     Area A is the lower one third of the anterior  
5     vaginal wall 12 (i.e. the one third nearest the  
6     entrance to the vaginal cavity) adjacent the bladder  
7     13 and urethra 14. Prolapse in this area is  
8     referred to as anterior or, more specifically,  
9     urethracele prolapse. Area B is the upper two  
10    thirds of the anterior vaginal wall 12. Prolapse in  
11    this area is referred to as anterior or, more  
12    specifically, cystocoele prolapse. The central area  
13    of the vaginal wall 12 in which the cervix 10 is  
14    located is adjacent the uterus 15 and prolapse in  
15    this area is referred to as central, uterine or  
16    vault prolapse. Area C is the upper one third of  
17    the posterior vaginal wall 12. This area of the  
18    vaginal wall 12 is adjacent the small bowel 16 and  
19    prolapse in this area is referred to as posterior or  
20    entrectocoele prolapse. Finally, area D is the lower  
21    two thirds of the posterior vaginal wall and is  
22    adjacent the rectum 17. Prolapse in this area is  
23    generally referred to as posterior or rectocoele  
24    prolapse.

25  
26    Conventionally, any of the above types of hernia  
27    have been treated by providing sutures in the area  
28    of the prolapse. For example, the extent of the  
29    defect causing the prolapse is first identified by  
30    the surgeon. Lateral sutures, i.e. sutures from one  
31    side to the other of the vaginal wall 12 as seen in  
32    figure 5 or right to left rather than anterior to

1 posterior, are provided across the area of the  
2 defect. This joins the parted tissues of the  
3 vaginal wall and repairs the defect. The organ  
4 protruding through the vaginal wall is therefore  
5 contained. Disadvantages of this technique include  
6 anatomical distortion of the vagina due to  
7 tensioning of the wall by the sutures to repair the  
8 defect.

9  
10 A surgical implant for use in the repair of vaginal  
11 prolapse in accordance with an embodiment of the  
12 present invention comprises a mesh 20. The mesh is  
13 comprised of strands 22. The strands being less  
14 than 600  $\mu\text{m}$  and approximately 150 to 600  $\mu\text{m}$  in  
15 diameter. The strands are arranged such that they  
16 form a regular network and are spaced apart from  
17 each other such that for a diamond net a space of  
18 between 2mm to 5mm exists between the points where  
19 the strands of the mesh interact with each other  
20 (a). In a hexagonal net arrangement the space is  
21 between 2mm to 5mm between opposite diagonal points  
22 where the strands of the mesh interact (b).

23  
24 It is preferable to space the strands as far as part  
25 as possible to allow blood to pass through the  
26 implant and reduce the mass of the implant, while  
27 providing the mesh with sufficient tensile strength  
28 and elasticity to be effective. It can therefore be  
29 appreciated that considerable variability in the  
30 maximum spacing between the strands can be achieved  
31 depending of the material from with the strands are

1     comprised and the net pattern in which the strands  
2     are arranged.

3

4     In the embodiment shown in figure 7a the strands are  
5     arranged in a diamond net pattern 24, however any  
6     pattern which provides suitable tensile strength and  
7     elasticity may be used.

8

9     For example a hexagonal net pattern may be used as  
10    shown in figure 7b.

11

12    Ideally in order to reduce the overall mass of the  
13    implant the strands 22 should have as narrow a  
14    diameter as possible while still providing the mesh  
15    20 with suitable tensile strength and elasticity.

16

17    The strands 22 of the mesh 20 are comprised of at  
18    least two filaments 26 arranged to interact such  
19    that pores 28 are formed between the filaments 26.

20

21    The pores 28 formed between the filaments 26 are  
22    around 50 to 200  $\mu\text{m}$ , such a spacing allowing  
23    fibroblast through growth to occur. This fibroblast  
24    through growth secures the implant 20 in place  
25    within the body. Additionally and importantly the  
26    suitably sized pores allow the implant 20 to act as  
27    a scaffold to encourage the lay down of new tissue.  
28    The lay down of new tissue promotes the healing of  
29    the hernia.

30

31    The filaments 26 may be formed from any  
32    biocompatible material. In this embodiment the

1     filaments 26 are formed from polyester, wherein each  
2     polyester filament 26 is around 0.09 mm in diameter.

3

4     In the embodiment shown the filaments 26 of the  
5     strands 24 are knitted together using warp knit to  
6     reduce the possibility of fraying of the filaments  
7     26 and strands 24.

8

9     Alternative suitable materials of which the  
10    filaments may be formed include polypropylene.

11

12    Suitable materials from which the mesh can be made:  
13    provide sufficient tensile strength to support a  
14    fascial wall during repair of a defect in the  
15    fascial wall causing a hernia; are sufficiently  
16    inert to avoid foreign body reactions when retained  
17    in the human body for long periods of time; can be  
18    easily sterilised to prevent the introduction of  
19    infection when the mesh is implanted in the human  
20    body; and have suitably easy handling  
21    characteristics for placement in the desired  
22    location in the body.

23

24    The fine warp knit of the filaments 26 provides a  
25    surgical implant which is flexible in handling, which  
26    can be easily cut into different shapes and  
27    dimensions. As the strands 24 are formed using warp  
28    knit the possibility of fraying of the edge of the  
29    surgical implant 20 following production or cutting  
30    of the surgical implant 20 is reduced.

31

1 Other methods of reducing fraying of the filaments  
2 24, not arranged to form the strands using warp  
3 knit, following cutting or production of the implant  
4 are heat treatment, laser treatment or the like to  
5 seal the edges of the surgical implant.

6

7 The mesh 20 may be supplied in any shape or size and  
8 cut to the appropriate dimensions as required by the  
9 surgeon.

10

11 It can be appreciated that cutting of the mesh will  
12 produce an unfinished edge 30. Due to the sparse  
13 nature of the strands that form the mesh and their  
14 narrow diameter this unfinished edge does not suffer  
15 from the same problems as edges of meshes of the  
16 prior art.

17

18 In other words the edge produced is not rough and  
19 jagged such that it increases the likelihood of  
20 extrusion of the edge of the mesh *in situ* or the  
21 chance of infection.

22

23 As discussed an advantage of the mesh of the present  
24 invention is that it allows the production of a mesh  
25 suitable for use in hernia repair which allows  
26 substantially less foreign material to be left into  
27 the body.

28

29 However, the mesh being flexible and insubstantial  
30 is less suitable for allowing easy handling of the  
31 mesh directly by a surgeon. Referring to figure 8a

1 and 8b the mesh described above may be treatable  
2 using an absorbable coating 32.

3  
4 The absorbable coating 32 comprises a layer of  
5 absorbable material having a thickness greater than  
6 that of the strands 22 of the mesh 20. For example,  
7 the thickness of the layer of absorbable material  
8 may be around 1 to 2 mm. The strands 22 of the mesh  
9 20 may be entirely embedded in the absorbable  
10 coating 32 such that the outer surface of the mesh  
11 20 is covered entirely of the absorbable coating 32.

12  
13 In effect the entire surgical implant is encased in  
14 the absorbable coating as shown in figure 8b.

15  
16 Thus, the surgical implant has no gaps or holes on  
17 its surface. This has the advantage of reducing the  
18 likelihood of bacteria becoming lodged on the  
19 strands 22 of the mesh 20 before implantation of the  
20 mesh 20. Furthermore, the absorbable coating 32  
21 makes the mesh 20 more substantial and less flexible  
22 such that it is more easily handled by a surgeon.  
23 This is particularly useful when it is desired to  
24 place the mesh in a desired location in a  
25 conventional, open surgical procedure.

26  
27 In an alternative embodiment shown in figure 8a the  
28 absorbable coating 32 comprises a layer of  
29 absorbable material applied to one face 34 of the  
30 mesh 20, such that the mesh has a first face 34 on  
31 which the absorbable material has been applied and a  
32 second face 36 on which the absorbable material has

1 not been applied such that the first and second  
2 faces 34 and 36 each have different characteristics.

3

4 It can also be envisaged that the surgical implant  
5 is provided with improved surgical handling  
6 qualities by a range of other methods. Such methods  
7 including, the releasable attachment of the mesh 20  
8 to a backing strip 40. This embodiment is shown in  
9 figure 8c.

10

11 The backing strip may be formed from plastics  
12 material and is adhered to the surgical implant  
13 using releasable adhesive.

14

15 In a similar fashion to the absorbable coating the  
16 backing strip 40 causes the mesh 20 to be more  
17 substantial and less flexible such that it is more  
18 easily handled by a surgeon. Following the suitable  
19 placement of the mesh 20 the backing strip 40 can be  
20 removed from the mesh 20, the mesh 20 being retained  
21 in the body and the backing material 40 being  
22 removed by the surgeon. Application of the backing  
23 strip 40 to the mesh 20 means the mesh 20 benefits  
24 from reduced mass but that the mesh 20 and backing  
25 strip 40 together give characteristics required for  
26 surgical handling.

27

28 In a further embodiment the filaments of the mesh  
29 may be comprised from bicomponent microfibres 50 or  
30 composite polymers 60. These technologies provide  
31 the implant with dual phase technology.

32



1 As shown in figure 8d the bicomponent microfibres 50  
2 comprise a core 52 (cutaway section shows core  
3 region) and surface material 54. The surface  
4 material 54 is designed such that it is absorbed by  
5 the body in a matter of hours, while the core  
6 material 52 remains in the body for a longer period  
7 to enable tissue ingrowth.

8  
9 Suitable bicomponent microfibres 50 include a  
10 polypropylene non absorbable portion and a polylactic  
11 acid absorbable portion.

12  
13 The surface material 54 is present during the  
14 surgical procedure when the mesh 20 is being  
15 inserted and located in the patient, and provides  
16 the mesh with characteristics desirable for surgical  
17 handling. Following a period of insertion in the  
18 body, typically a few hours, the surface material 54  
19 is absorbed into the body leaving only the core  
20 material 52 of the filaments 26 in the body. The  
21 core material of the filament having reduced foreign  
22 mass in comparison to meshes of the prior art or the  
23 mesh 20 when it also includes the surface material  
24 54.

25  
26 As shown in figure 8e the mesh of the surgical  
27 implant may be formed composite polymers 60. As  
28 described for the bicomponent microfibres 50,  
29 composite polymers 60 provide the surgical implant  
30 with dual phase technology. A first face 62 of the  
31 mesh 20 thus having particular characteristics such  
32 as flexibility and elasticity, while a second face

1 64 of the mesh 20 provides the mesh 20 with  
2 characteristics which improved the surgical handling  
3 of the mesh 20 such as strength and robustness.  
4 The cutting of the mesh described causes an  
5 unfinished edge of the mesh to be produced. This  
6 unfinished mesh not being as likely to cause the  
7 same problems as the rough and jagged edges of the  
8 implants of the prior art, due to the fewer strands,  
9 smaller diameter filaments and treatment of the mesh  
10 with absorbable coating which protects the tissue  
11 from the mesh during the surgical procedure when  
12 damage is most likely to occur.

13  
14 Referring to 9a, a further embodiment of the mesh  
15 may comprise strands as discussed and more  
16 specifically, perimeter strands. Typically the mesh  
17 is circular or the like in shape and thus this  
18 perimeter strand can be generally referred to as a  
19 circumferential strand 70.

20  
21 In the example shown in figure 9a one strand runs  
22 around the circumference of the oval shape of the  
23 mesh 20. In another embodiment, several  
24 circumferential strands 70 may be present, each  
25 circumferential strand 70 may extend over one side  
26 of the oval mesh 20, i.e. around half the  
27 circumference of the mesh.

28  
29 As shown in figure 9b the circumferential strands 70  
30 are arranged concentrically and each extends around  
31 the mesh 20 at a different radial location.  
32

1 An outer circumferential strand 70 extending around  
2 the perimeter of the mesh 20, and further  
3 circumferential strands 72 and 74 are arranged  
4 inwardly of the outer circumferential strand forming  
5 a perimeter spaced by a distance (a). The distance  
6 a between adjacent circumferential members 70, 72  
7 and 74, can vary and in this example is 20 mm.

8  
9 Transverse strands 76 extend from the centre of the  
10 oval mesh 20 to points on the perimeter of the mesh  
11 78. In this example, four transverse strands 76 are  
12 provided across the diameter of the mesh 20,  
13 dividing the mesh 18 into eight angularly equal  
14 portions.

15  
16 The mesh 20 of this embodiment may be formed from  
17 materials as previously described. Depending on the  
18 material chosen the mesh may be woven, knitted or  
19 extruded as one piece, or individual or groups of  
20 strands can be extruded separately and joined to one  
21 another.

22  
23 Such a construction as described above provides a  
24 mesh 20 with sufficient tensile strength to repair  
25 defects causing vaginal prolapse whilst having  
26 minimal bulk. Similarly, such a construction  
27 provides a suitably flexible yet resilient mesh for  
28 handling using the surgical tools described below.  
29 Referring to figures 9c and 9d, meshes 80, 82 of in  
30 the shape of the outline having angled sides  
31 respectively, rather than oval, are illustrated.

32

1     These meshes have a similar structure to that  
2     described with reference to figure 9a and b.  
3     However, the mesh has a perimeter member 80 having  
4     angled sides. Further it may have transverse  
5     members arranged only to extend towards the  
6     perimeter of the mesh, rather than all being across  
7     the diameter of the mesh. This provides a more  
8     uniform structure. More specifically, referring to  
9     figure 9d the mesh has a transverse member 84  
10    extending along its axis of symmetry, a transverse  
11    member 86 bisecting the axis of symmetry, and four  
12    further transverse members 88 extending from the  
13    axis of symmetry to the perimeter of the mesh 90.

14

15    In addition to the pores provided by the combination  
16    of filaments 26 which form the strands 22, pores can  
17    be provided by rings of polypropylene positioned at  
18    the intersection of the circumferential and  
19    transverse members.

20

21    Alternatively the pores may be formed by the spacing  
22    of the transverse members, such that pores of a size  
23    50-200µm suitable for enabling tissue ingrowth exist  
24    between the transverse members.

25

26    To secure the mesh to a suitable location in the  
27    body a number of methods can be used. The tackiness  
28    of the absorbable coating may hold the mesh suitably  
29    until it is secured by tissue ingrowth.

30

31    Alternatively the surgical implant can have capsules  
32    100(not shown) of biocompatible glue for securing

1 the mesh 20 in place. In this example, six capsules  
2 100 comprising spheres having a diameter of 4 mm and  
3 made from a rapidly absorbable material are provided  
4 around the perimeter of the mesh 20. On placement  
5 in the body, the capsules 100 dissolve and release a  
6 biocompatible glue contained within to secure the  
7 mesh 20 in place.

8  
9 Referring to figure 10, a tool 200 for inserting one  
10 of the meshes described (usually without an  
11 absorbable coating 32) comprises two channels 202,  
12 204. The channels 202, 204 are semi-circular in  
13 cross-section and the channel 202 has a diameter  
14 slightly smaller than the diameter of channel 204.  
15 The channels are interconnected such that the  
16 channel 202 can be rotated inside the channel 204.  
17 In use, the mesh 20 is rolled up and placed in the  
18 space formed by the channels 202, 204 in a first  
19 position in which the open sides of the channels  
20 face one another to form a housing or tube. After  
21 insertion into the desired location, channel 204 is  
22 rotated inside the channel 202 to release the mesh  
23 20.

24  
25 Referring to figure 11, an alternative tool 210 for  
26 inserting one of the meshes described comprises an  
27 elongate housing 212 around which the mesh is rolled  
28 and secured. The tool 210 has means for trapping an  
29 edge of the mesh 20 to secure it on the housing of  
30 the tool 212, such as a groove 214. In use, once  
31 the mesh 20 has been rolled around the housing of  
32 the tool 210 it may be secured by a removable clip

1 or other such retaining means (not shown). After  
2 insertion of the tool 210 into the desired location,  
3 the mesh 20 is released and the tool 210 is rotated  
4 to unfurl the mesh 20.

5

6 Referring to figure 12, another alternative tool 220  
7 for inserting one of the meshes described above in  
8 the body comprises two arms 222 pivotally  
9 interconnected by a pivot 224. One end of each arm  
10 226 has means for being releasably attached to the  
11 mesh 20. The other end of each arm 228 is operable  
12 to move the ends that may be attached to the mesh 20  
13 toward or away from one another by rotation around  
14 the pivot 224. When the ends of the arms 226,228 to  
15 which the mesh 20 can be attached are moved to a  
16 position in which they are close to one another, the  
17 tool 220 is substantially elongate. Furthermore,  
18 the mesh 20 is radially confined by the arms. Once  
19 the mesh 20 has been inserted into position, the  
20 arms 226,228 can be manipulated to move the ends to  
21 which the mesh 20 can be attached apart to unfurl  
22 the mesh 20 in its intended position.

23

24 Referring to figure 13, another tool 230 for  
25 inserting one of the meshes described above in its  
26 desired location comprises an elongate housing 232  
27 having a number of pairs of holes 234 spaced along  
28 its length (in this example three pairs) at the  
29 distal end of the tool 230. The housing 232 is  
30 hollow and contains a number (in this case three) of  
31 pairs of wires 236, made from polypropylene for  
32 example, which extend along the length of the

1 housing 232 and out through the pairs of holes 234.  
2 The wires 236 also protrude from the proximal end of  
3 the housing such that they can be pushed and pulled  
4 in and out of the housing 232. The ends of the  
5 wires 236 that protrude from the holes 234 have  
6 means for releasably attaching to points near the  
7 perimeter of the mesh 20.

8  
9 In use, the wires 236 are attached to the mesh 20  
10 and retracted by pulling them back through the  
11 housing 30 such that the mesh 20 is radially  
12 confined close to the housing 232. Once the tool  
13 230 has been inserted into the intended position,  
14 the wires 236 are pushed into the housing 232 and  
15 consequently out through the holes 234 to urge the  
16 mesh 20 away from the housing 232. Thus, the mesh  
17 20 can be unfurled in its desired location in the  
18 body.

19  
20 Referring once again to figure 5 in order to repair  
21 a urethracocele prolapse i.e. a defect in the area A  
22 of figure 5, the surgeon first locates the defect by  
23 examining the patient in the conventional manner.  
24 The extent of the defect can then be ascertained  
25 and, if necessary, a suitable template used to  
26 estimate the shape and dimensions of a preferred  
27 surgical implant to repair the defect. A suitably  
28 shaped surgical implant can then be selected.

29  
30 The meshes described above are, in this example,  
31 supplied in a single size. After examination of the  
32 patient and estimation of the desired dimensions of

1 the preferred mesh, the surgeon cuts the mesh to the  
2 preferred size.

3

4 Where the mesh comprises a circumferential member 70  
5 the cut made in the mesh is through the transverse  
6 members 76 just outward of the circumferential  
7 member 70 corresponding most closely with the  
8 preferred size of mesh. Thus, regardless of the  
9 size to which the mesh is to be cut, a  
10 circumferential member 70 defines the perimeter of  
11 the mesh, and the perimeter of the mesh is  
12 substantially smooth. This desirably reduces the  
13 likelihood of infection or edge erosion once the  
14 mesh is inserted in the body.

15

16 The surgeon then attaches the mesh to or inserts the  
17 mesh with one of the insertion tools described  
18 herein. For example, the mesh is rolled up and  
19 placed within the insertion tool 200 illustrated in  
20 figure 10, wrapped around the insertion tool 210  
21 illustrated in figure 11, attached to the ends of  
22 the arms 222 of the insertion tool 220 illustrated  
23 in figure 12 or attached to the ends of the wires  
24 236 of the insertion tool 230 illustrated in figure  
25 13.

26

27 An incision 9 is then made in the vaginal wall 12 at  
28 the forward most portion of the vaginal wall 12  
29 adjacent the opening of the vaginal cavity. A  
30 cutting implement (not illustrated), such as  
31 scissors or a specialised cutting tool, is/are then  
32 inserted through the incision 9 into the area A,



1 i.e. the lower portion of the anterior vaginal wall  
2 12. Using the cutting implement, a cut is made in  
3 the area A parallel with the surface of the vaginal  
4 wall 12. In other words, a space is opened up in  
5 the vaginal wall 12 over the area of the defect in  
6 the vaginal wall 12. The cutting implement is then  
7 withdrawn and the mesh 20 is inserted in the space  
8 defined by the cut.

9  
10 Where the insertion tool 200 illustrated in figure  
11 10 is used, the tool 200 is inserted into the area A  
12 and the channel 202 rotated to a position within the  
13 channel 204 to release the mesh 20. The insertion  
14 tool 200 can then be retracted and the mesh unfurls  
15 due to its inherent resilience or flat memory.  
16 Should it be required to help the mesh 20 to unfurl,  
17 or slightly re-position the mesh 20 defect 2, an  
18 elongate tool (not shown) may be inserted through  
19 the incision 9 or needles may be introduced directly  
20 through the vaginal wall 12 to manipulate the mesh  
21 20. This procedure can be viewed laproscopically  
22 through the incision 9 if desired.

23  
24 Where the insertion tool 210 illustrated in figure  
25 11 is used, it is desirable for the insertion tool  
26 210 to be inserted to one side of the space defined  
27 by the cut. The mesh 20 is then released and a  
28 needle inserted through the vaginal wall to hold the  
29 released edge of the mesh 20 in position. The tool  
30 210 is then rolled across the space defined by the  
31 cut in an arc having a centre of rotation around the  
32 incision 9. Thus, the mesh 20 is unfurled, but no

1 significant movement is required around the incision  
2 9.

3  
4 Where the insertion tool 220 illustrated in figure  
5 12 is used, the insertion tool 220 is simply  
6 inserted through the incision 9 and opened to expand  
7 the mesh 20 into its desired location. The mesh 20  
8 is released from the insertion tool 220 which can  
9 then be closed and withdrawn through the incision 9.

10  
11 Finally, where the insertion tool 250 illustrated in  
12 Figure 13 is used, the mesh 20 is retracted by  
13 withdrawing the wires 236 through their holes 234  
14 and the mesh is inserted through the incision 9.  
15 Once the insertion tool 230 has been inserted into  
16 its desired location, the wires 236 are urged  
17 forward and out through the holes 234 to expand the  
18 mesh in its intended position. The wires 236 can  
19 then be released from the mesh 20, withdrawn into  
20 the housing 232 and the tool 230 withdrawn through  
21 the incision 9.

22  
23 Once the mesh 20 is in place, the incision may be  
24 closed.

25  
26 However, it can be desirable to secure the 20 in  
27 place, rather than rely on the mesh 20 remaining in  
28 its desired location of its own accord. In one  
29 example, sutures are therefore be placed either  
30 laproscopically through the incision 9 or directly  
31 through the vaginal wall 12 to hold the mesh 20 in  
32 place. In another example, glue capsules provided

1 on the mesh 20 dissolve to secure the mesh 20 to the  
2 tissue surrounding the space defined by the cut, or  
3 such capsules may be punctured by needles inserted  
4 directly through the vaginal wall 12.

5

6 The surgical implant described herein is  
7 advantageous over the meshes of the prior art in  
8 several ways.

9

10 In particular the mesh of the present invention  
11 includes smoother edges, the polyester material of  
12 the present invention being softer than  
13 polypropylene. Further, the filaments of the  
14 present invention are narrower in diameter enabling  
15 them to be more pliable than the strands of the  
16 meshes of the prior art. This causes the edge or  
17 edges of the mesh of the present invention to have  
18 fewer jagged edges and thus be smoother than the  
19 edges of meshes of the prior art.

20

21 In addition encasement of the mesh in an absorbable  
22 coating further protects the tissue both during  
23 placement and for a period of time after placement  
24 of the surgical implant.

25

26 Dual Phase Technology™ such as encasement in an  
27 absorbable coating or as otherwise discussed herein  
28 provides the implant with good handling  
29 characteristics, further it enables the implant to  
30 be more easily cut. As described above an  
31 absorbable coating may protect the tissues around  
32 where the implant is to be located both during

1 placement and for a period of time following  
2 placement of the implant in the tissue.

3

4 Dual Phase Technology™ may also provide the implant  
5 with memory. This memory may allow the implant to  
6 be more easily placed flat on the tissue. Further  
7 the dual phase technology such as an absorbable  
8 coating may provide the implant with mild adhesive  
9 properties or tackiness which would aid both the  
10 locating and securing of the implant in the tissue.

11

12 The surgical implant described herein thus allows  
13 tension free repair of hernias, particular vaginal  
14 prolapse, with minimum pain. This allows the  
15 procedure to be performed under local anaesthetic in  
16 an out patient or office setting.

17

18 Whilst the above embodiments of the invention have  
19 been described with reference to vaginal prolapse,  
20 the mesh and surgical tools may equally be used to  
21 repair any bodily hernia. Furthermore, whilst the  
22 above procedure has been described in relation to a  
23 urethrocoele prolapse, prolapse in other parts of  
24 the vaginal wall can be treated through incisions  
25 elsewhere in the vaginal wall, or other bodily  
26 hernias through suitable incisions in the  
27 appropriate tissue.

1     **Claims**

2

3     1.    A surgical implant suitable for treatment of  
4     hernias, the implant comprising a mesh comprising  
5     strands having a maximum residual mass density of  
6     50g/m<sup>2</sup>.

7

8     2.    An implant as claimed in claim 1 wherein the  
9     mesh has a maximum residual mass density of less  
10    than 30g/m<sup>2</sup>.

11

12    3.    A surgical implant as claimed in claims 1 or 2  
13    wherein the mesh comprises strands and includes  
14    major spaces and pores, the spaces existing between  
15    the strands and pores formed within the strands.

16

17    4.    An implant as claimed in any preceding claim  
18    wherein strands are formed from at least two  
19    filaments.

20

21    5.    A surgical implant as claimed in any preceding  
22    claim wherein the strands are spaced apart to form  
23    major spaces of 1 to 10 mm.

24

25    6.    A surgical implant as claimed in any preceding  
26    claim wherein the strands have a diameter of less  
27    than 600µm.

28

29    7.    A surgical implant as claimed in any preceding  
30    claim wherein the strands are arranged to form a  
31    warp knit diamond or hexagonal net mesh.

32

1     8.    A surgical implant as claimed in any preceding  
2     claim wherein the strands are arranged to form a net  
3     mesh which has isotropic or near isotropic tensile  
4     strength and elasticity.

5  
6     9.    A surgical implant as claimed in any preceding  
7     claim wherein the filaments have a diameter of  
8     between 0.02 to 0.15 mm.

9  
10    10.   A surgical implant as claimed in any preceding  
11    claim wherein the filament of the mesh is of a  
12    diameter 0.05 to 0.1 mm.

13  
14    11    A surgical implant as claimed in any preceding  
15    claim wherein a monofilament or at least two  
16    filaments are interwoven/knitted such that the  
17    strands of the mesh comprise pores.

18  
19    12.   A surgical implant as claimed in any preceding  
20    claim wherein the pores in the strands are of  
21    between 50 to 200 $\mu$ m in diameter.

22  
23    13.   A surgical implant as claimed in any preceding  
24    claim further comprising rings of material  
25    comprising pores of between 50 to 200 $\mu$ m adhered to  
26    on the strands of the mesh to provide pores.

27  
28    14.   A surgical implant as claimed in any preceding  
29    claim wherein the pores in the strands are of  
30    between 50 to 75 $\mu$ m in diameter.

31

1 15. A surgical implant as claimed in any preceding  
2 claim wherein the filaments of the mesh comprise a  
3 plastics material.  
4

5 16. A surgical implant as claimed in any preceding  
6 claim wherein the filaments of the mesh comprise a  
7 synthetic material.  
8

9 17. A surgical implant as claimed in any preceding  
10 claim wherein the filaments of the mesh comprise an  
11 absorbable material.  
12

13 18. A surgical implant as claimed in any of claims  
14 1 to 16 wherein the filaments of the mesh comprise  
15 polypropylene.  
16

17 19. A surgical implant as claimed in any of claims  
18 1 to 16 wherein the filaments of the mesh comprise  
19 polyester.  
20

21 20. A surgical implant as claimed in any preceding  
22 claim wherein the implant has an absorbable coating  
23 which degrades within 48 hours.  
24

25 21. A surgical implant as claimed in claim 20  
26 wherein the absorbable coating encapsulates the mesh  
27 of the surgical implant.  
28

29 22. A surgical implant as claimed in claim 20  
30 wherein the absorbable coating is applied to at  
31 least one face of the mesh.  
32

1     23. A surgical implant as claimed in claims 20 to  
2     22 wherein the absorbable coating comprises any  
3     suitable soluble and biocompatible material.

4  
5     24. A surgical implant as claimed in claims 20 to  
6     23 wherein the absorbable coating is a soluble  
7     hydrogel such as gelatin.

8  
9     25. A surgical implant as claimed in claims 20 to  
10    23 wherein the absorbable coating is a starch or  
11    cellulose based gel.

12  
13    26. A surgical implant as claimed in claims 20 to  
14    23 wherein the absorbable coating is an alginate.

15  
16    27. A surgical implant as claimed in claims 20 to  
17    26 wherein the coating is of a thickness greater  
18    than that of the mesh.

19  
20    28. A surgical implant as claimed in any preceding  
21    claim comprising a backing strip wherein the backing  
22    strip is releasably attachable to the mesh.

23  
24    29. A surgical implant as claimed in claim 28  
25    wherein the backing strip is formed from plastics.

26  
27    30. A surgical implant as claimed in claims 28 or  
28    29 wherein the surgical implant is releasably  
29    attachable to the backing strip by adhesive.

30



1 31. A surgical implant as claimed in any preceding  
2 claim wherein the strands of the mesh are comprised  
3 of bicomponent microfibres.

4  
5 32. A surgical implant as claimed in claim 31  
6 wherein the bicomponent microfibres comprise a core  
7 and surface material.

8  
9 33. A surgical implant as claimed in claim 32  
10 wherein the surface material is capable of being  
11 absorbed by the body in a period of less than 48  
12 hours.

13  
14 34. A surgical implant as claimed in claims 32 or  
15 33 wherein the core material is capable of remaining  
16 in the body for a period of time sufficient to  
17 enable tissue ingrowth.

18  
19 35. A surgical implant as claimed in claim 32  
20 wherein the surface material is polylactic acid and  
21 the core material is polypropylene.

22  
23 36. A surgical implant as claimed in any preceding  
24 claim wherein the surgical implant comprises  
25 material that has memory.

26  
27 37. A surgical implant as claimed in claim 36  
28 wherein the surgical implant has memory which urges  
29 the surgical implant to adopt a flat conformation.

30

1 38. A surgical implant as claimed in any preceding  
2 claim wherein the implant has a generally curved  
3 perimeter.

4  
5 39. A surgical implant as claimed in any preceding  
6 claim wherein the surgical implant is of width  
7 between 1 cm to 10 cm and of length between 1 cm to  
8 10 cm.

9  
10 40. A surgical implant as claimed in any preceding  
11 claim wherein the implant is any one of round,  
12 circular, oval, ovoid elliptical or truncated  
13 elliptical or some similar shape.

14  
15 41. A surgical implant as claimed in any preceding  
16 claim wherein the mesh can be cut to any desired  
17 shape.

18  
19 42. A surgical implant as claimed in any preceding  
20 claim wherein the mesh has at least one  
21 circumferential member which extends, in use, along  
22 at least part of the perimeter of the implant to  
23 provide a substantially smooth edge.

24  
25 43. A surgical implant as claimed in claim 42  
26 wherein at least part of the perimeter of the  
27 implant is defined by the circumferential member.

28  
29 44. A surgical implant as claimed in claims 42 or  
30 43 wherein at least 50% of the perimeter of the  
31 implant is defined by the circumferential member(s).

32

1 45. A surgical implant as claimed in claims 42 to  
2 44 wherein at least 80% of the perimeter of the  
3 implant is defined by the circumferential member(s).  
4

5 46. A surgical implant as claimed in claims 42 to  
6 45 wherein 100% of the perimeter of the implant is  
7 defined by the circumferential member(s).  
8

9 47. A surgical implant as claimed in claims 42 to  
10 46 wherein the perimeter of the mesh is defined, in  
11 use, by one circumferential member.  
12

13 48. A surgical implant as claimed in claims 42 to  
14 47 wherein the mesh has a plurality of  
15 circumferential members arranged at different radial  
16 locations.  
17

18 49. A surgical implant as claimed in claim 48  
19 wherein the circumferential members are arranged to  
20 join with one another in order to form an integral  
21 mesh.  
22

23 50. A surgical implant as claimed in claim 42 to 49  
24 wherein the mesh comprises transverse members which  
25 extend across the circumferential members joining  
26 the circumferential members.  
27

28 51. A surgical implant as claimed in claim 50  
29 wherein the transverse members extend radially from  
30 a central point to the perimeter of the implant.  
31

1     52. A surgical implant as claimed in claim 50 or 51  
2     wherein the transverse members extend toward the  
3     perimeter of the implant.

4  
5     53. A surgical implant as claimed in any preceding  
6     claim wherein the mesh can be glued in place using a  
7     biocompatible glue.

8  
9     54. A surgical implant as claimed in any preceding  
10    claim comprising at least one capsule containing  
11    biocompatible glue for securing the implant in  
12    place.

13  
14    55. A surgical implant as claimed in claim 54  
15    comprising four capsules containing glue provided  
16    around the perimeter of the surgical implant.

17  
18    56. A surgical implant as claimed in claims 54 or  
19    55 wherein the capsules comprise hollow thin walled  
20    spheres of around 3 to 5 mm diameter including  
21    gelatin.

22  
23    57. A surgical implant as claimed in claims 54 to  
24    56 wherein the glue is a cyanoacrylate glue.

25  
26    58. A minimally invasive method of treating  
27    uterovaginal prolapse, the method comprising the  
28    steps;

29  
30       making a 1-2cm length incision in the vaginal  
31       wall close to the opening of the vaginal cavity  
32       and,

1 making a subcutaneous cut, through the  
2 incision, over and surrounding the area of the  
3 prolapse, which cut is substantially parallel  
4 to the vaginal wall; and  
5  
6 inserting a mesh according to the present  
7 invention, through the incision, into the space  
8 defined by the cut.

9

10 59. A method of treating uterovaginal prolapse as  
11 claimed in claim 58 wherein the incision is at the  
12 posterior extremity of the prolapse sac of the  
13 vaginal cavity.

14

15 60. A method of treating uterovaginal prolapse as  
16 claimed in claim 58 wherein the incision is at the  
17 anterior extremity of the prolapse sac of the  
18 vaginal cavity.

19

20 61. A surgical tool for delivering a surgical  
21 implant as described in claims 1 to 57  
22 subcutaneously through an incision, the tool being  
23 adapted to radially confine the surgical implant  
24 during delivery and being operable to release the  
25 mesh in its intended position.

26

27 62. A surgical tool as claimed in claim 61  
28 comprising a housing and unfurling means the housing  
29 and unfurling means insertable through an incision  
30 in the patient, the housing and unfurling means  
31 adapted to accommodate a rolled up mesh and  
32 separable to release the mesh, the unfurling means

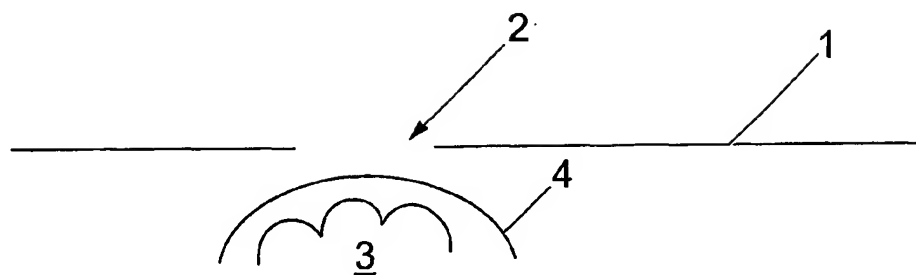
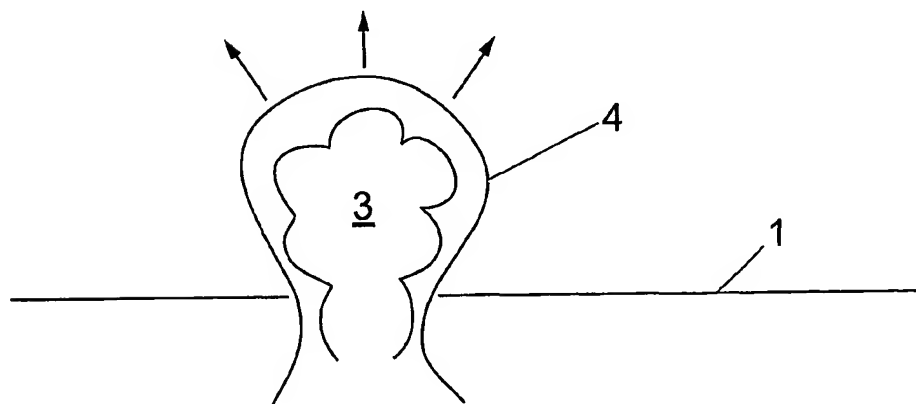
61

1 capable of unfurling the rolled up mesh without any  
2 significant movement around the area of the incision  
3

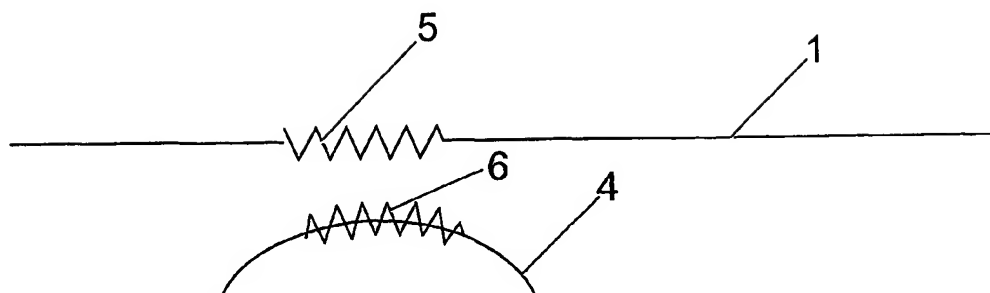
4 63. A surgical tool as claimed in claim 61 or 62  
5 comprising two or more parts, the parts movable such  
6 that in a first position they house the mesh or  
7 surgical implant and, in a second position the mesh  
8 or surgical implant is released. More preferably  
9 the tool comprises two semi-circular channels, an  
10 inner channel having an external diameter suitable  
11 for fitting inside an outer channel.  
12

13 64. Use of an implant as claimed in any of claims 1  
14 to 57 in the treatment of inguinal hernia,  
15 incisional hernia or uterovaginal prolapse.

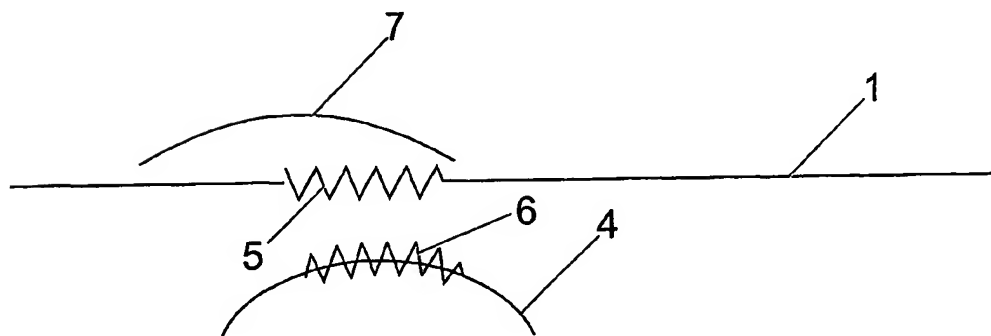
1 / 10

*Fig. 1**Fig. 2*

2 / 10



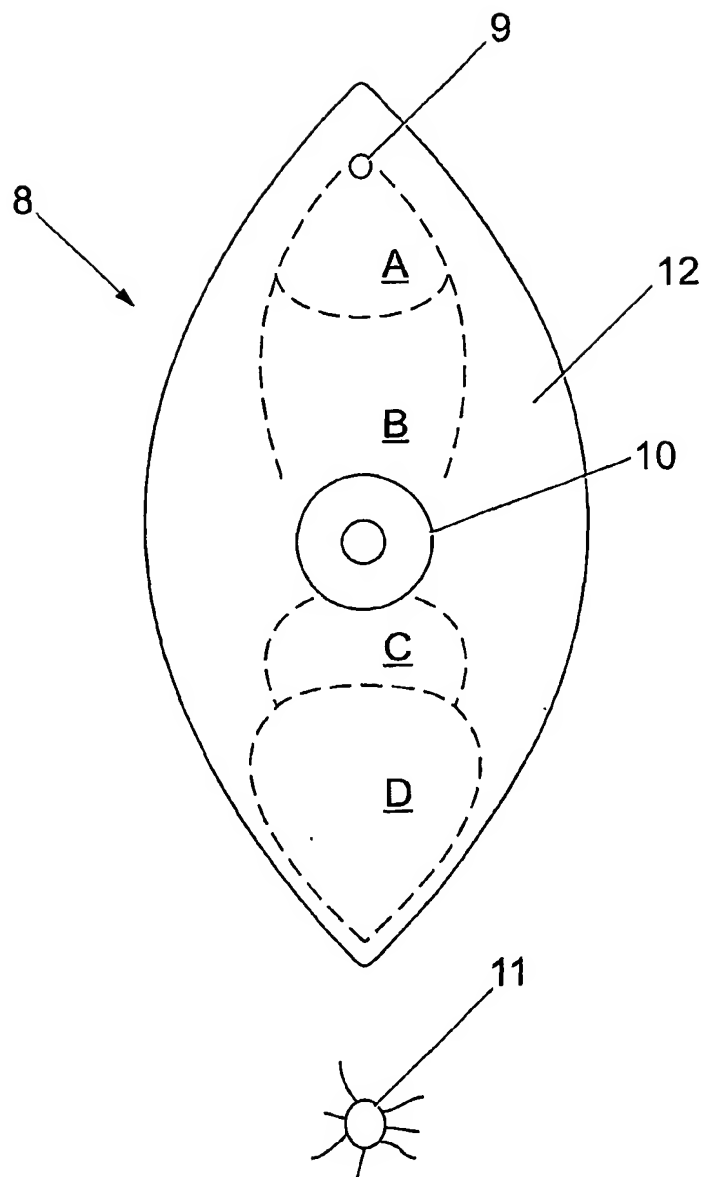
*Fig. 3*



*Fig. 4*



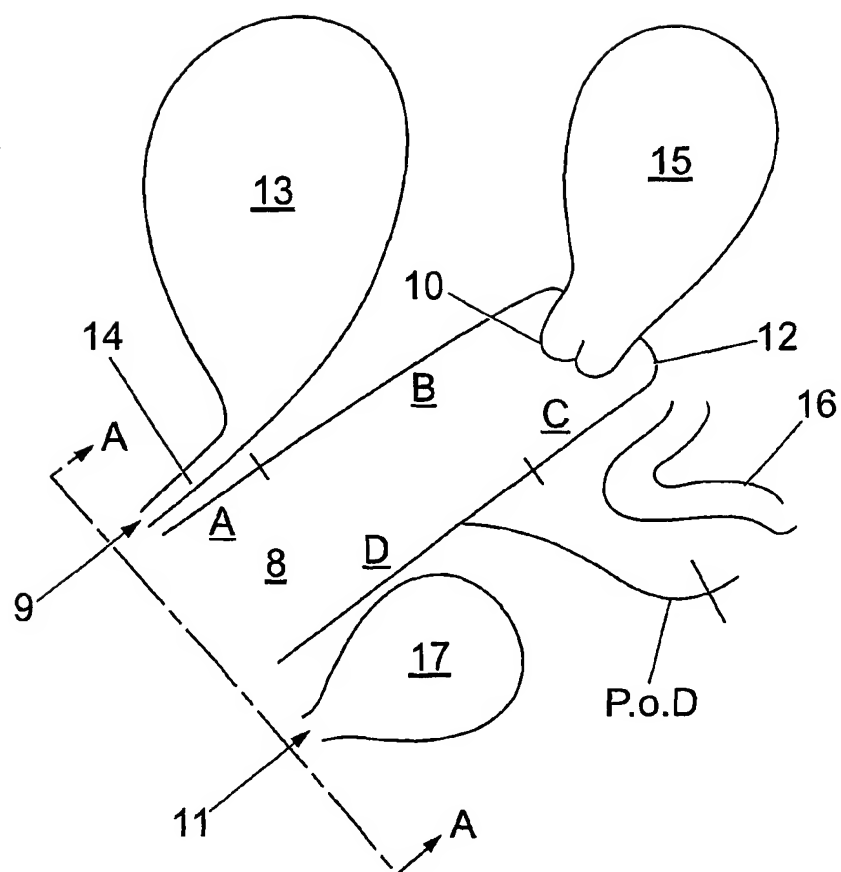
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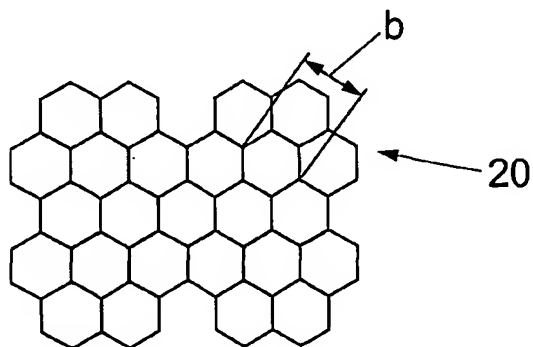
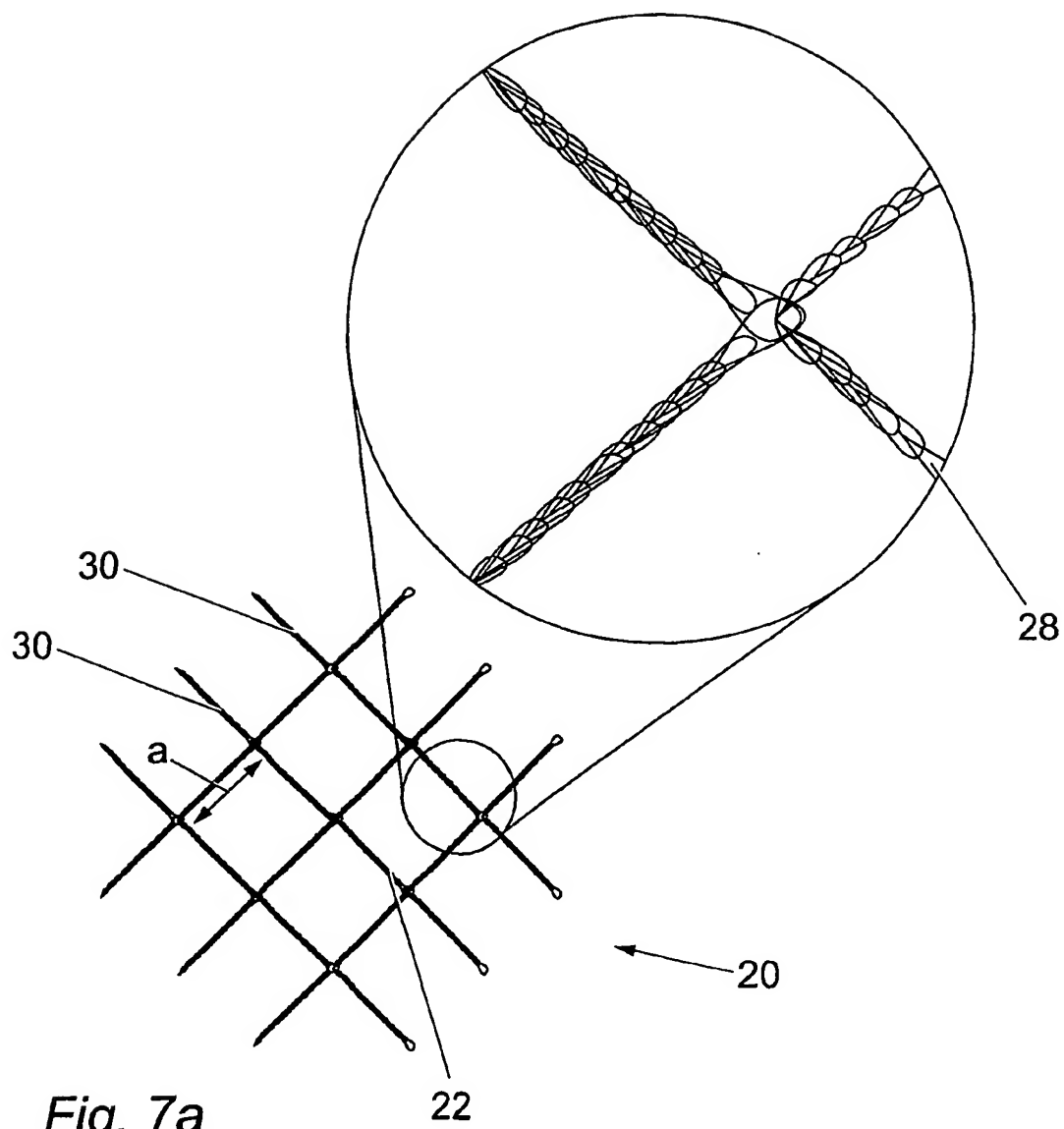
SECTION A-A

*Fig. 5*

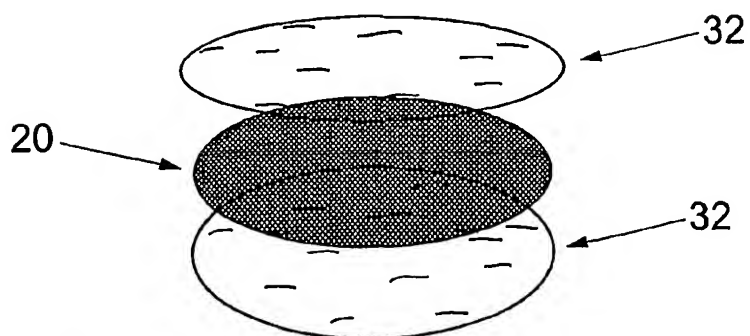
4 / 10

*Fig. 6*

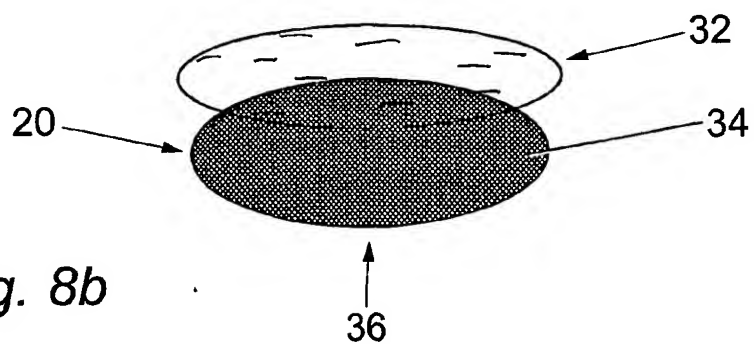
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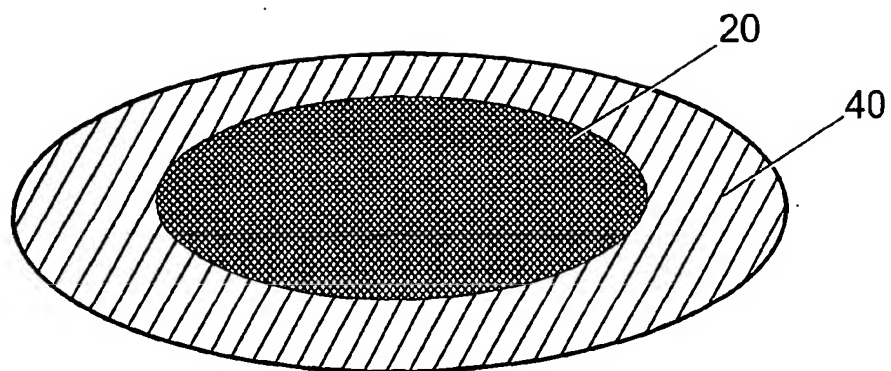
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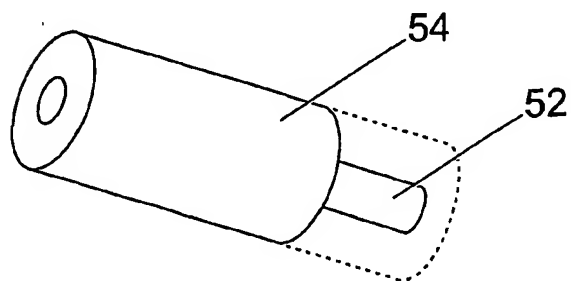
*Fig. 8a*



*Fig. 8b*

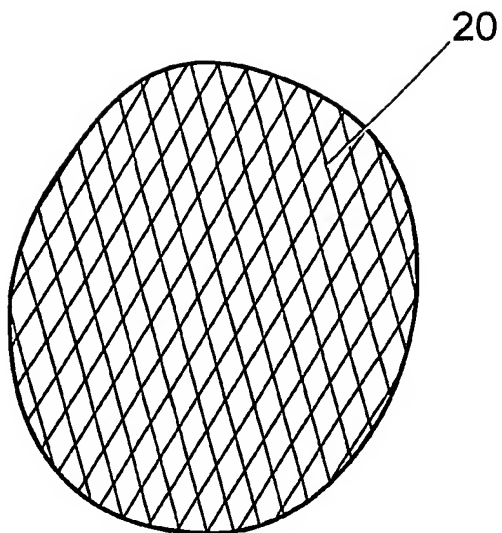


*Fig. 8c*

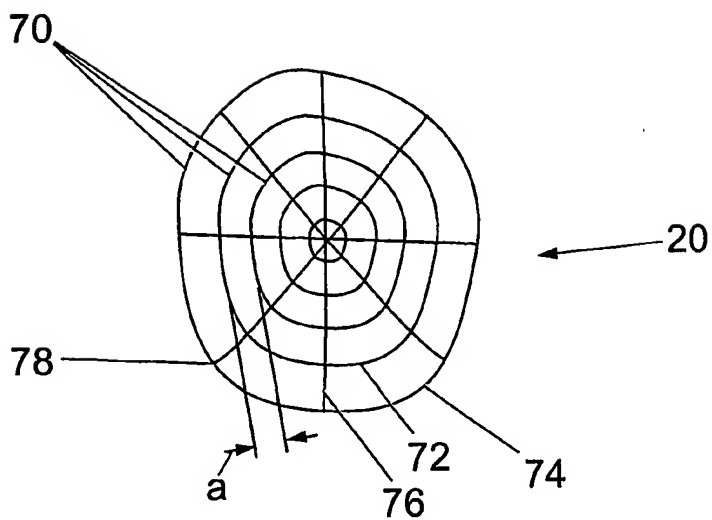


*Fig. 8d*

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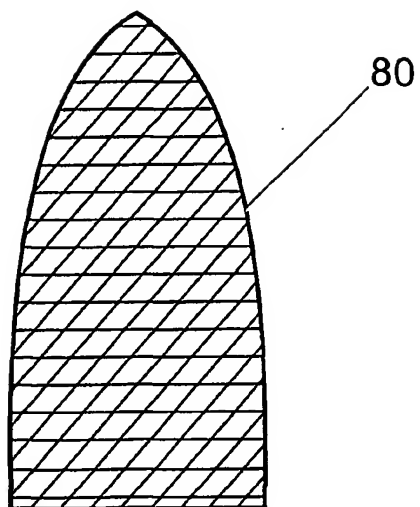


*Fig. 9a*

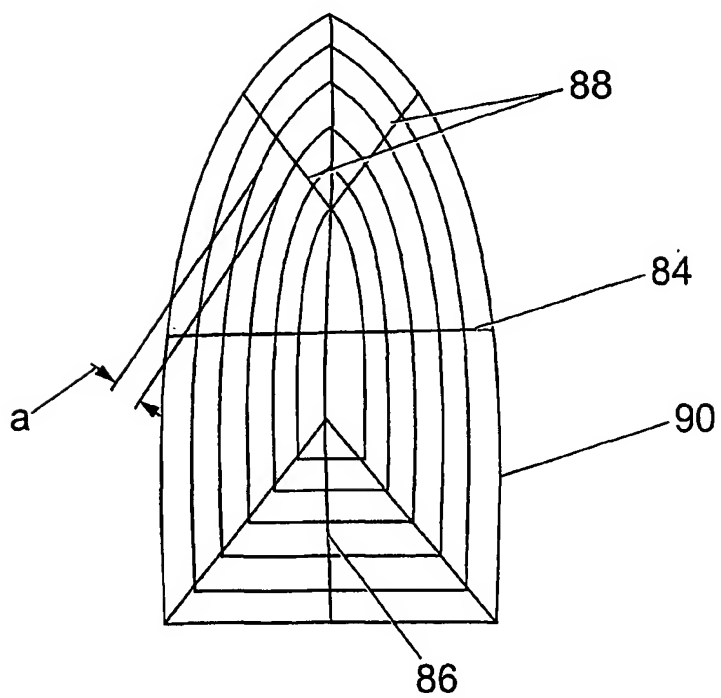


*Fig. 9b*

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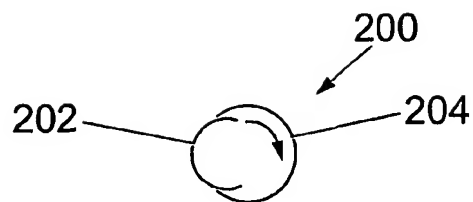


*Fig. 9c*

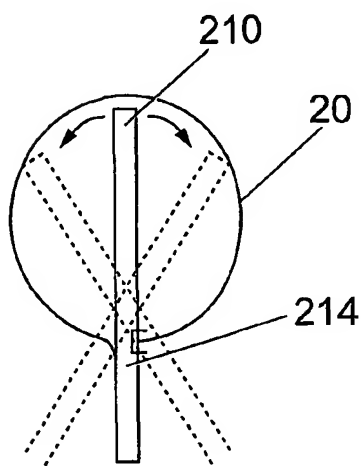


*Fig. 9d*

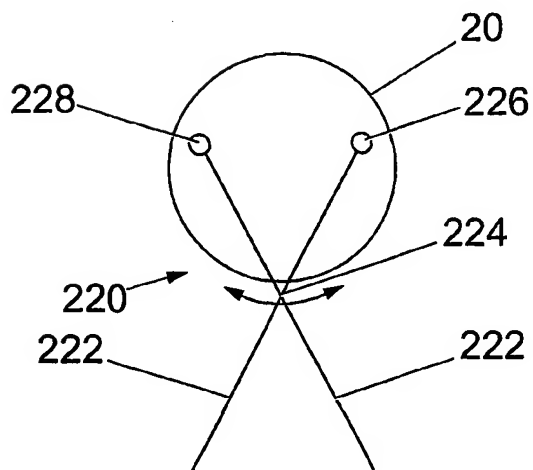
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*Fig. 10*

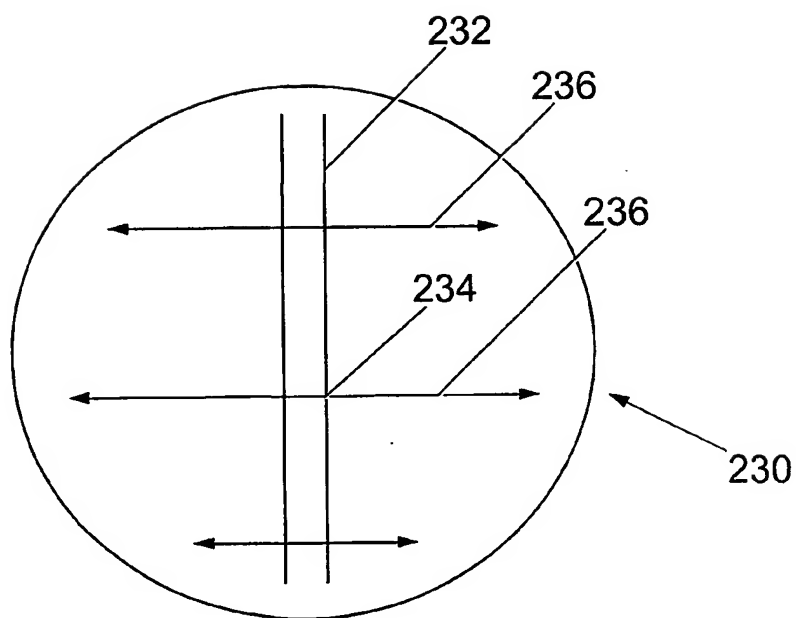


*Fig. 11*



*Fig. 12*

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*Fig. 13*



# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/GB 02/01234

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	abstract	15, 20-24, 36, 38-45, 47-53, 57, 61-63
Y	page 4, line 1 -page 5, line 32; table WO 00 07520 A (PELISSIER EDOUARD) 17 February 2000 (2000-02-17)	15, 38-45, 47-52
A	page 8, line 31 -page 9, line 2; figures -/-	3, 7, 16

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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Date of mailing of the international search report

05/06/2002

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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 02/01234

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